Biotechnology Research Program: Assessing the Potential Allergenicity of Foods Derived from Genetically Engineered Crops

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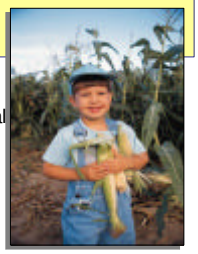
Why are Genetically Engineered Crops of Concern to EPA?

- Biotechnology is used to develop new products for agricultural pest control via incorporation of genetic material for novel proteins into plants and microorganisms.
- Pesticidal proteins have been incorporated into plants such as corn, potatoes, cotton, and tomatoes.
- Research to develop assessment tools is needed in order to investigate susceptibility and to improve risk assessment for dietary allergy.



Determining Potential Risks to Human Health

The EPA Office of Prevention, Pesticides, and Toxic Substances (OPPTS) regulates the use of all pesticides in the U.S., including genetically introduced plant-incorporated protectants (PIPs) and biopesticides. OPPTS establishes maximum levels for pesticide residues and evaluates human and ecological health risks under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA) using all available information.

- Is the source of the trait associated with reports of allergenicity?
- Is the amino acid sequence similar to that of known allergens?
- How quickly is the protein digested?
- What is the protein's prevalence in food?
- Are there results from specific serum screening tests?

OPP has identified the development of animal models of allergenicity as a critical research need and has worked with ORD to establish a research program in biotechnology to investigate potential models.

Office of Research and Development Collaborates on Research to Improve Animal Models of Allergenicity

Methods to predict potential allergenicity of novel proteins introduced into the diet can be improved. Research is being conducted in the Office of Research and Development (ORD) by the National Health and Environmental Effects Laboratory (NHEERL) and coordinated with a Science-to-Achieve Results (STAR) Program solicitation to develop animal models and predictive methods to assess allergenicity of novel dietary proteins.

National Health and Environmental Effects Research Laboratory (NHEERL)

Research Goal: Develop a dietary allergy model in laboratory rodents.

Approach: Generate allergic responses in rodents through oral exposure to proteins which are allergenic in humans. Use the model to determine potential allergenicity of novel proteins relative to known allergens, explore the role of digestibility, identify susceptibility factors in early development, and elucidate the general mechanisms underlying allergic sensitization to dietary proteins.

National Center for Environmental Research (NCER)

Research Goal: Develop methods to assess human allergenicity of proteins in GE foods and improve understanding of basic mechanisms underlying food allergy and susceptibility.

Approach: Solicit research proposals through the Science to Achieve Results (STAR) Program and award up to seven grants or cooperative agreements.

NHEERL Biotechnology Research	NCER STAR Program in Biotechnology
 Develop an animal model for human dietary allergy (disease) ⇩ ■ Understand mechanisms underlying dietary allergies ■ Relate digestibility to allergenicity ■ Identify endpoints for use in an animal screening model ■ Determine potency relative to known allergens ■ Identify windows of vulnerability during early development	■ TITLE: Biotechnology: Potential Allergenicity of Genetically Engineered Foods ■ OPEN DATES: Dec. 14, 2005 to Mar. 21, 2006 ■ DATE OF PEER REVIEW: Apr. 26, 2006 ■ EARLIEST PROJECT START DATE: Aug., 2006 ■ FUNDING: Maximum of $600,000 per grant ■ GRANT DURATION: 3 Years ■ Collaborations between laboratory scientists and grant principal investigators can be supported under cooperative agreements and include activities such as data and information exchange, providing technical input to experimental design and theoretical development, coordinating extramural research with in-house activities, sharing of samples and equipment, and joint authorship of journal articles on these activities.

Anticipated Outputs and Outcomes

The projected output of this collaboration between NHEERL and NCER under the Biotechnology Research Program is an animal model to predict allergenicity of novel proteins. The projected outcomes are an improved ability to assess potential risks to human health from PIPs in foods derived from GE crops and an overall improvement in the knowledge of food allergens.

The opinions expressed herein are strictly those of the authors and do not reflect U.S. EPA policy.

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